



IFW

PTO/SB/21 (07-06)  
Approved for use through 09/30/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/590,300
	Filing Date	August 23, 2006
	First Named Inventor	Eric T. Fossel
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	Attorney Docket Number	S1509.70037US01

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard
<b>Remarks</b>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	WOLF, GREENFIELD & SACKS, P.C.		
Signature			
Printed name	Tani Chen, Sc.D.		
Date	January 17, 2007	Reg. No.	52,728

Certificate of Mailing Under 37 CFR 1.8(a)	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
Dated: 1/17/07	Signature:  (Angela M. Griffith)



DOCKET NO.: S1509.70037US01

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Eric Thor Fossel  
Serial No.: 10/590,300  
Confirmation No.: Not yet assigned  
Filed: August 23, 2006  
For: TOPICAL DELIVERY OF A NITRIC OXIDE DONOR TO  
IMPROVE BODY AND SKIN APPEARANCE

Examiner: Not yet assigned  
Art Unit: Not yet assigned

---

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 17<sup>th</sup> day of January, 2007.

  
Angela M. Griffith

---

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 C.F.R. §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing of a first Office action on the merits in the above-identified case.

No fee or certification is required.

Serial No.: 10/590,300  
Conf. No.: Not Yet Assigned

- 2 -

Art Unit: Not Yet Assigned

## PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>	<u>Atty. Docket No.</u>
08/932,227	September 17, 1997	Eric T. Fossel	S1509.70029US00
10/201,635	July 22, 2002	Eric T. Fossel	S1509.70029US01
10/213,286	August 5, 2002	Eric T. Fossel	S1509.70026US02
11/587,323	October 19, 2006	Eric T. Fossel	S1509.70038US00
11/587,328	October 19, 2006	Eric T. Fossel	S1509.70039US00

## PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified PTO/SB/08):

FR 5940 is generally directed to a drug containing citric acid and arginine.

FR 2602678 is generally directed to an aqueous pharmaceutical composition based on magnesium, sodium and potassium salts for the regulation of blood circulation.

FR 2740453 is generally directed to L-lysine and L-arginine peptide mixtures for cosmetic use.

JP 9/241156 is generally directed to a blood flow promotor and a preparation for external use for skin containing the same.

## PART IV: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1112350.1

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:



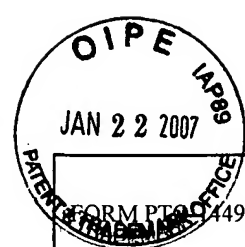
Tani Chen, Sc.D., Reg. No. 52,728  
Patrick R.H. Waller, Ph.D., Reg No. 41,418  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: S1509.70037US01

Date: January 17, 2007

**xNDDx**

1112350.1



FORM PTO/A-449/A and B (modified PTO/SB/08)

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

APPLICATION NO.: 10/590,300      ATTY. DOCKET NO.: S1509.70037US01

FILING DATE: August 23, 2006      CONFIRMATION NO.: Not yet assigned

APPLICANT: Eric Thor Fossel

GROUP ART UNIT: Not yet assigned      EXAMINER: Not yet assigned

Sheet 1 of 3

## **U.S. PATENT DOCUMENTS**

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		4,681,897		L. Brand	07-21-1987
		4,732,892		Sarpotdar, et al.	03-22-1988
		4,871,839		Gibson	10-03-1989
		5,028,435		Katz, et al.	07-02-1991
		5,391,550		Carniglia et al.	02-21-1995
		5,405,919		Keefer et al.	04-11-1995
		5,428,070		Cooke et al.	06-27-1995
		5,476,852		Cauwenbergh	12-19-1995
		5,505,958		Bello, et al.	04-09-1996
		5,538,740		Abad	07-23-1996
		5,543,430		Kaesemeyer	08-06-1996
		5,576,351		Yoshimura, et al.	11-19-1996
		5,595,753		H. Hechtman	01-21-1997
		5,629,002		Weuffen, et al.	05-13-1997
		5,632,981		Saavedra, et al.	05-27-1997
		5,648,101		Tawashi	07-15-1997
		5,691,423		Smith et al.	11-25-1997
		5,698,738		Garfield et al.	12-16-1997
		5,714,472		Gray, et al.	02-03-1998
		5,789,442		Garfield et al.	08-04-1998
		5,853,768		Altadonna	12-29-1998
		5,891,459		Cooke et al.	04-06-1999
		5,895,658		Fossel	04-20-1999
		5,922,332		Fossel	07-13-1999
		5,925,372		Berner et al.	07-20-1999
		6,103,275		Seitz et al.	08-15-2000
		6,117,872		Maxwell, et al.	09-12-2000
		6,207,713	B1	Fossel	03-27-2001
		6,448,267	B1	Anggard et al.	09-10-2002
		6,451,337	B1	Smith et al.	09-17-2002
		6,458,841	B2	Fossel	10-01-2002
		6,511,991	B2	Hrabie et al.	01-28-2003
		6,538,033	B2	Bing	03-25-2003
		6,617,337	B1	Wilcox	09-09-2003
		2002/0041903		Fossel	04-11-2002
		2002/0168424		Mohsen, et al.	11-14-2002
		2003/0018076		Fossel	01-23-2003
		2003/0028169		Fossel	02-06-2003

FORM PTO-1449/A and B (modified PTO/SB/08)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/590,300	ATTY. DOCKET NO.: S1509.70037US01	
				FILING DATE: August 23, 2006	CONFIRMATION NO.: Not yet assigned	
				APPLICANT: Eric Thor Fossel		
				GROUP ART UNIT: Not yet assigned	EXAMINER: Not yet assigned	
Sheet	2	of	3			

#### FOREIGN PATENT DOCUMENTS

		FR	5940		Dufour, C.	04-08-1968	N
		FR	2602678		Drouault, G.	02-19-1988	N
		FR	2740453	A1	Bieurope Societe Anonyme	04-30-1997	N
		JP	9/241156	A	Noevir Co Ltd	09-16-1997	N
		JP	04-005231		Takagi Hiroshi [Abstract Only]	09-01-1992	Abstract
		WO	94/09750	A1	Unilever N.V.	05-11-1994	
		WO	95/13060		Frolich, Jurgen, et al.	05-18-1995	Abstract
		WO	96/08966	A1	New York Society For The Ruptured And Crippled Maintaining The Hospital For Special Surgery	09-21-1995	
		WO	97/16983		The Board of Trustees of the Leland Stanford Junior University	05-15-1997	
		WO	99/13717	A1	Strategic Sciences & Technologies Inc.	03-25-1999	
		WO	2005/081964	A2	Strategic Science & Technologies, LLC	09-09-2005	
		WO	2005/102282	A1	Strategic Science & Technologies, LLC	11-03-2005	
		WO	2005/102307	A2	Strategic Science & Technologies, LLC	11-03-2005	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		ARGIOLAS, A., "Nitric Oxide is a Central Mediator of Penile Erection," <i>Neuropharmacology</i> , Vol. 33, No. 11, pp. 1339-1344 (1994).	
		BIRDER, et al., "Adrenergic and capsaicin evoked nitric oxide release from urothelium and afferent nerves in urinary bladder," <i>American Journal of Physiology</i> , Vol. 275, pp. F226-F229 (1998). [Abstract only]	
		BUNKER, C.B., et al., "Alterations in scalp blood flow after the epicutaneous application of 3% minoxidil and 0.1% hexyl nicotinate in alopecia," <i>Correspondence</i> , pp. 668-669 (1986).	
		COOPER, et al., "Transdermal Delivery of Drugs," <i>CRC Press</i> , Vol. II, pp. 57-62 (1987).	
		DE BOER, E.M., et al., "Does Topical Minoxidil Increase Skin Blood Flow?," <i>Acta Derm Venereol</i> , Vol. 68, pp. 271-274 (1988).	
		DIETZ, N.M., et al., "Is nitric oxide involved in cutaneous vasodilation during body heating in humans?" <i>J. Appl. Physiol</i> , Vol. 76, No. 5, pp. 2047-2053 (1994).	
		GARBAN, H., et al., "Effect of aging on nitric oxide-mediated penile erection in rats," <i>Am. J. Physiol.</i> , H467-H475 (1995).	
		HWANG, T.I., et al., "Evaluation of Vasculogenic Impotence Using Dynamic Penile Washout Test," <i>J. Formosan Med. Assoc.</i> , Vol. 89, No. 11, pp. 992-996 (1990).	
		KIRKEBY, H.J., et al., "Role of the L-arginine/nitric oxide pathway in relaxation of isolated human penile cavernous tissue and circumflex veins," <i>Acta Physiol Scand.</i> , Vol. 149, pp. 385-392 (1993).	
		KLEMP, P., et al., "Subcutaneous Blood Flow in Early Male Pattern Baldness," <i>J. Invest. Dermatol.</i> , 92, pp. 725-726 (1989).	
		LAAN, E., et al., "Assessment of female sexual arousal: Response specificity and construct validity," <i>Psychophysiology</i> , Vol. 32, pp. 476-485 (1995).	
		MATHIAS, B. J., et al., "Topical Capsaicin for Chronic Neck Pain," <i>Am. J. Phys. Rehabil.</i> , Vol. 74, pp. 39-44 (1995).	

FORM PTO-1449/A and B (modified PTO/SB/08)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/590,300	ATTY. DOCKET NO.: S1509.70037US01
				FILING DATE: August 23, 2006	CONFIRMATION NO.: Not yet assigned
				APPLICANT: Eric Thor Fossel	
				GROUP ART UNIT: Not yet assigned	EXAMINER: Not yet assigned
Sheet	3	of	3		

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

	MOODY, J.A., et al., "Effects of Long-Term Oral Administration of L-arginine on the Rat Erectile Response," <i>The Journal of Urology</i> , Vol. 158, pp. 942-947 (1997).	
	OWEN, J.A., et al., "Topical Nitroglycerin: A Potential Treatment for Impotence," <i>The Journal of Urology</i> , Vol. 143, pp. 546-548 (1989).	
	PAULY, et al., "Liposomes containing amino acids and peptides and proteins for skin care," (1998) [Abstract only]	
	RIEDEL, et al., "Different Mechanisms Of L-Arginine Induced Dilation Of Brain Arterioles In Normotensive And Hypertensive Rats", CA: 122 (11) 130053t [Abstract only]	
	SINGH, S., et al., "Response of digital arteries to endothelium dependent and independent vasodilators in patients with Raynaud's phenomenon," <i>European Journal of Clinical Investigation</i> , Vol. 25, pp. 182-185 (1995).	
	SONNTAG, M., et al., "Role of nitric oxide in local blood flow control in the anaesthetized dog," <i>European Journal of Physiology</i> , pp. 194-199 (1992).	
	TSENG, L.F., et al., "Increase of nitric oxide production by L-arginine potentiates i.c.v. administered $\beta$ -endorphin-induced antinociception in the mouse," <i>European Journal of Pharmacology</i> , Vol. 212, pp. 301-303 (1992).	
	WANG, R. et al., "Nitric Oxide Mediates Penile Erection in Cats," <i>The Journal of Urology</i> , Vol. 151, pp. 234-237 (1994).	
	WHITMORE, E.S., et al., "Acute Effect of Topical Minoxidil on Digital Blood Flow in Patients with Raynaud's Phenomenon," <i>The Journal of Rheumatology</i> , Vol. 22, No. 1, pp. 50-54 (1995).	
	International Preliminary Report on Patentability for International Application No. PCT/US2005/005726 dated August 30, 2006.	
	International Search Report for International Application No. PCT/US05/13230 dated October 28, 2005.	
	International Search Report for International Application Serial No. PCT/US98/19429, international filing date September 17, 1998	
	International Search Report for International Application Serial No. PCT/US05/13228 dated July 5, 2005	
	Written Opinion for International Application No. PCT/US05/13230 dated October 28, 2005.	
	Written Opinion for International Application No. PCT/US2005/005726 dated August 30, 2006.	
	Written Opinion for International Application Serial No. PCT/US05/13228 dated July 5, 2005.	
EXAMINER:		DATE CONSIDERED:

# EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]